NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

February 28, 2000

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, Maryland 20852

Re: Docket No. 99N-2497; Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action; 64 Federal Register 66822; November 30, 1999.

Dear Sir or Madam:

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA's members produce processed and packaged fruits, vegetables and grain products, meat, poultry, and seafood products, snacks, drinks, and juices. In addition NFPA's non-processor members provide ingredients, equipment, supplies, and services to the processed food industry.

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As announced in the above referenced Federal Register notice, FDA is proposing to amend its regulation pertaining to Citizen Petitions. NFPA understands FDA's resource problem and agrees that the Citizen Petition process should be improved. However, the proposed action would frustrate the purposes and objectives of the Federal Food, Drug, and Cosmetic Act (FFDCA) by limiting the ability of regulated companies and consumers to seek amendment of the agency's regulations, regardless of their substance, and other appropriate administrative action in a meaningful and legally binding way. The proposed changes will not eliminate frivolous petitions or petitions that request actions the agency cannot take legally or would not consider for good policy reasons. Moreover, none of the proposed changes will relieve the agency of its obligation to review and respond to any petitions properly filed. Proposing to change a system that has facilitated reasonably effective public participation in the agency's rulemaking and related processes for more than twenty years poses a real risk of creating possibly unintended and undesirable consequences. Instead, NFPA recommends the agency use its limited resources to refine and implement the existing citizen petition process more efficiently.

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The FDA regulates all aspects of food safety and commerce. Restricting Citizen Petitions to handle only food safety issues is too limiting. Limiting this course of action would result in an absence of an effective equivalent mechanism to handle commercial issues that have significant consumer deception implications.

Specifically, proposed §10.30(e)(2)(ii) – "Denial of Citizen Petitions" would provide that FDA's denial of a citizen petition may be "brief, as appropriate." At 64 FR 66824, FDA provides examples where the agency envisions a brief response denying a petitioner's request may be appropriate. The list includes:

"3. A citizen petition where the agency has determined that the petition does not implicate a significant public health issue, and the agency lacks the resources to provide a more detailed response or to take the action requested by the petitioner. This may occur, for example, where the petitioner requests a change in FDA's regulations that has no significant public health implications, such as amending or establishing common or usual names regulations or standards of identity, quantity, and fill of container regulations for foods.... In the absence of a significant public health issue, and considering the intense demand on FDA's resources, the agency must allocate its resources carefully and wisely, so brief denial of these types of citizen petitions would be appropriate."

Similarly, proposed § 10.30(e)(4)(i)(D) would allow FDA to refer a Citizen Petition "for other administrative action instead of issuing a response" if the Petition "[d]oes not involve a significant public health or consumer protection issue."

Granting FDA the ability to dismiss summarily a legitimate request to amend or establish common or usual name regulations or standards of identity can eliminate the only recourse available to a company seeking to develop a new product. Granting FDA the ability to refer such a request "for other administrative action" would have the same functional result. Indeed, seeking to amend a standard of identity is the only means a company has for marketing a new form of a product covered by a standard of identity. FDA has maintained that the only acceptable course of action for marketing a product which is different from the product described in the standard of identity is by seeking and obtaining a Temporary Marketing Permit (TMP) under 21 CFR §130.17. The regulations (§130.17(b)) state that: "It is the purpose of the Food and Drug Administration to permit such tests when it can be ascertained that the sole purpose of the tests is to obtain data necessary for reasonable grounds in support of a petition to amend food standards..." Thus the only legitimate reason for obtaining the permit is to seek an amendment to the standard of identity. FDA's proposal would permit the Agency to reject a request for a temporary marketing permit on the grounds that the Agency has insufficient resources to address any Citizen Petition that might ensue from such a permit.

There is concern that FDA may elect to use this amendment to eliminate existing Citizen Petitions to reduce their backlog. This fear is well founded as NFPA received a request to withdraw its Citizen Petition to amend the standard of identity for Canned Pacific Salmon (21 CFR §161.170). The original petition was submitted May 13, 1988 (Docket

No. 88P-0190/CP1) with an amended Citizen Petition filed June 10, 1989 (88P-0190/CP2). The petition was filed on behalf of the US canned salmon industry after lengthy discussions with the agency. The agency determined that the proposed new style of pack (skinless, boneless salmon) could not be marketed as a non-standardized food even with appropriate labeling to reveal how it differed from the standard. The only recourse was to submit a Citizen Petition to amend the standard. This would permit individual companies to request a TMP to pack the item while the petition was under review. Several firms obtained TMP's and packed product under those agreements with each TMP announced in the Federal Register. On August 15, 1988 (53 FR 30716), FDA announced the extension of the expiration date of a temporary permit to market test canned skinless and boneless chunk salmon packed in water until either the effective date of a final rule for any proposal to amend the standard of identity for canned Pacific salmon which may result from the NFPA petition or 30 days after the termination of such proposal.

When NFPA received the request to withdraw the Citizen Petition we inquired as to the status of any TMP's currently in effect for the product. The response was that "they would no longer be in effect." We then inquired whether the agency would reconsider its position with respect to permitting continued sale of the product as a non-standardized food provided it were labeled appropriately. The answer was "no, the product can no longer be sold." On the basis of this response we rejected the agency request that we withdraw the Citizen Petition.

Based on this situation we feel compelled to oppose the agency's contention that the decision on whether the standards of identity regulations should be amended be based solely to accommodate current allocation of agency resources. Indeed, in NFPA's comments of September 30, 1999 to Docket No. 98N-0359, 64 FR 47845, the Association stated, in part:

"In addition to these priorities, NFPA believes that CFSAN should assign to food standards of identity some place on its prioritization scheme. Maintenance of the regulatory framework for food standards is important for both consumers and the food industry...A number of the existing standards presently serve as barriers to the utilization of new technologies and ingredients to improve existing products. This, in turn, has made it difficult for the U.S. to promote an effective U.S. position at recent Codex Committee meetings, in light of the outmoded standards now in place..."

NFPA notes that, for fiscal year 2000, FDA has included an item related to food standards of identity on the priority list of FDA's Center for Food Safety and Applied Nutrition (CFSAN). Item 2 on the "B" List for Strategy 2.2 – Nutrition, Health Claims and Labeling, is to "develop a coordinated plan between FDA and USDA to correlate existing food standards with current technological innovations." This demonstrates that food standards of identity are indeed, in FDA's view, worthy of the allocation of some resources.

NFPA also advises FDA that creating obstacles to amending food standards of identity so as to render any such changes impracticable, a likely consequence of a rule resulting from the Citizen Petition initiative as proposed, would not remove the Agency's statutory authorities and obligations, or industry's rights, with respect to food standards of identity. Section 401 of the FFDCA provides for the establishment of these standards, and NFPA is unaware of any lawful means by which a procedural regulation can void authority under the statute.

Accordingly, NFPA requests that FDA expressly rescind the preamble language quoted above, from 64 FR 66824. NFPA further requests that FDA delete in its entirety proposed §10.30(e)(4)(i)(D) "Does not involve a significant public health or consumer protection issue." As stated earlier in these comments, one of the prerequisites for amending a standard of identity is that the amendment to the standard would not create a public health or consumer protection issue.

The food industry in general and NFPA in particular have strongly supported the allocation of additional resources for the CFSAN as a part of the appropriations process. We believe that the agency should allocate its available resources in such a way that it could address all of its responsibilities.

In summary NFPA opposes any FDA action to reject summarily a Citizen Petition based solely on the grounds that the Agency lacks sufficient resources to respond to the action requested. NFPA also opposes any FDA action to refer Citizen Petitions that do not involve significant public health or consumer protection issues for other administrative action, rather than responding.

Thank you for providing this opportunity to comment on this proposal.

Sincerely,

Allen W. Matthys, Ph.D.
Vice President
Regulatory Affairs